Listing of the Claims

1. (Original) An orally administrable formulation for administering nitrofurantoin to a patient in need thereof which comprises: a first component being a controlled release form and a second component being an immediate release form, wherein (a) said first component comprises nitrofurantoin monohydrate, sodium alginate, alginic acid and hypromellose; (b) said second component comprises macrocrystalline nitrofurantoin; and (c) said formulation provides a therapeutically effective combination of said nitrofurantoin monohydrate and said macrocrystalline nitrofurantoin.

2. (Original) The formulation of claim 1, wherein each of said first and second components independently is in the form selected from the group consisting of granules and powders and wherein said components are provided in a single dosage unit.

3. (Original) The formulation of claim 2, wherein said dosage unit is a tablet.

4. (Original) The formulation of claim 3, wherein said first and second components are present as separate layers.

5. (Original) The formulation of claim 2, wherein said dosage unit is a capsule.

6. (Original) The formulation of claim 1, wherein each of said components is in the form of one or more tablets and said tablets are encapsulated within a single capsule.

7. (Original) The formulation of claim 5, wherein each of said components in said capsule is in the form of granules or powders and said components are present as separate layers.

8. (Original) The formulation of claim 5, wherein one of said components in said capsule is in the form of at least one tablet and the other of said components in said capsule is in the form of granules or powders.

9. (Original) The formulation of claim 1, wherein each of said first and second components is provided as a separate dosage unit.

10. (Original) The formulation of claim 9, wherein each component is provided as at least one tablet.

11. (Original) The formulation of claim 1, wherein said first component comprises from about 25 mg to about 600 mg nitrofurantoin monohydrate.

12. (Original) The formulation of claim 11, wherein said first component comprises from about 50 mg to about 300 mg nitrofurantoin monohydrate.

13. (Original) The formulation of claim 12, wherein said first component comprises from about 75 mg to about 150 mg nitrofurantoin monohydrate.

14. (Original) The formulation of claim 11, wherein said second component comprises from about 5 mg to about 400 mg macrocrystalline nitrofurantoin.

15. (Original) The formulation of claim 14, wherein said second component comprises from about 12 mg to about 200 mg macrocrystalline nitrofurantoin.

16. (Original) The formulation of claim 15, wherein said second component comprises from about 25 mg to about 100 mg macrocrystalline nitrofurantoin.

17. (Original) The formulation of claim 1, wherein from about 5% to about 90% by weight of said first component is hypromellose.

18. (Original) The formulation of claim 17, wherein from about 5% to about 60% by weight of said first component is hypromellose.

19. (Original) The formulation of claim 18, wherein from about 10% to about 30% by weight of said first component is hypromellose.

20. (Original) The formulation of claim 1, wherein from about 2% to about 80% by weight of said first component is sodium alginate.

21. (Original) The formulation of claim 20, wherein from about 5% to about 60% by weight of said first component is sodium alginate.

22. (Original) The formulation of claim 21, wherein from about 10% to about 30% by weight of said first component is sodium alginate.

23. (Original) The formulation of claim 1, wherein from about 2% to about 80% by weight of said first component is alginic acid.

24. (Original) The formulation of claim 23, wherein from about 5% to about 60% by weight of said first component is alginic acid.

25. (Original) The formulation of claim 24, wherein from about 10% to about 30% by weight of said first component is alginic acid.

26. (Original) The formulation of claim 1, wherein said first component comprises nitrofurantoin monohydrate in an amount of about 20% by weight of said first component; hypromellose in an amount of about 20% by weight of said first component; sodium alginate in an amount of about 20% by weight of said first component; and alginic acid in an amount of about 20% by weight of said first component; and said second component comprises macrocrystalline nitrofurantoin in an amount of about 12.5% by weight of said second component; and said first component and said second component are present in a wt:wt ratio of about 1:1 to about 5:1.

27. (Original) The formulation of claim 1, wherein each of said first and second components further comprises at least one pharmaceutically acceptable carrier, provided that said carrier in said first component does not comprise polyvinylpyrrolidone or carboxyvinylpolymer.

28. (Original) The formulation of claim 27, wherein said carrier comprises a diluent, lubricant, surfactant, glidant or colorant.

29. (Original) The formulation of claim 1 or 26, wherein at least one of said first and second components is coated.

30. (Original) An orally administrable formulation for the administration of nitrofurantoin to a patient in need thereof which comprises: a first component being a controlled release form and a second component being an immediate release form, wherein (a) said first component comprises: nitrofurantoin monohydrate in an amount of from about 5% to about 50% by weight of said first component; hypromellose in an amount of from about 5% to about 90% by weight of said first component; sodium alginate in an amount of from about 2% to about 80% by weight of said first component; alginic acid in an amount of from about 2% to about 80% by weight of said first component; a diluent in an amount of from about 2% to about 90% by weight of said first component; and a lubricant in an amount of from about 0.1% to about 6% by weight of said first component; and (b) said second component comprises: macrocrystalline nitrofurantoin in an

amount of from about 3% to about 35% by weight of said second component; a diluent in an amount of from about 5% to about 90% by weight of said second component; and a lubricant in an amount of from about 0.1% to about 6% by weight of said second component; and said first and second components are present in a wt:wt ratio of from about 1:1 to about 5:1.

31. (Original) The formulation of claim 30, wherein said first or second component further comprises a colorant.

32. (Original) The formulation of claim 31, wherein said colorant is present in an amount of about 0.5% by weight of said second component.

33. (Original) The formulation of claim 30, wherein said first and second components are present in a wt:wt ratio of about 2:1.

34. (Original) The formulation of claim 30, wherein said diluent comprises microcrystalline cellulose, dibasic calcium phosphate, lactose, starch, sucrose or mannitol.

35. (Original) The formulation of claim 30, wherein said lubricant comprises magnesium stearate, talc, calcium oxide, zinc oxide, stearic acid, sodium stearyl fumarate or vegetable oil.

36. (Original) The formulation of claim 30, wherein at least one of said first and second components is coated.

37. (Original) An orally administrable formulation for the administration of nitrofurantoin to a patient in need thereof which comprises: a first component being a controlled release form and a second component being an immediate release form, wherein (a) said first component comprises: nitrofurantoin monohydrate in an amount of about 20% by weight of said first component; hypromellose in an amount of about 20% by weight of said first component; sodium alginate in an amount of about 20% by weight of said first component; and alginic acid in an amount of about 20% by weight of said first component; microcrystalline cellulose in an amount of about 9% by weight of said first component; dibasic calcium phosphate in an amount of about 10% by weight of said first component; and magnesium stearate in an amount of about 1% by weight of said first component; and (b) said second component comprises: macrocrystalline nitrofurantoin in an amount of about 12.5% by weight of said second component; lactose in an amount of about 43% by weight of said second component; microcrystalline cellulose in an amount of about 43% by weight of said second component; and magnesium stearate with sodium

lauryl sulfate in an amount of about 1% by weight of said second component; and said first and second components are present in a wt:wt ratio of from about 1:1 to about 5:1.

38. (Original) The formulation of claim 37, wherein said first or second component further comprises a colorant.

39. (Original) The formulation of claim 38, wherein said colorant is present in an amount of about 0.5% by weight of said second component.

40. (Original) The formulation of claim 37, wherein said first and second components are present in a wt:wt ratio of about 2:1.

41. (Original) The formulation of claim 30 or 37, wherein each of said first and second components independently is in the form selected from the group consisting of granules and powders and wherein said components are provided in a single dosage unit.

42. (Original) The formulation of claim 41, wherein said dosage unit is a tablet.

43. (Original) The formulation of claim 42, wherein said first and second components are present as separate layers.

44. (Original) The formulation of claim 37, wherein said dosage unit is a capsule.

45. (Original) The formulation of claim 37, wherein each of said components is in the form of one or more tablets and said tablets are encapsulated within a single capsule.

46. (Original) The formulation of claim 44, wherein each of said components in said capsule is in the form of granules or powders and said components are present as separate layers.

47. (Original) The formulation of claim 44, wherein one of said components in said capsule is in the form of at least one tablet and the other of said components in said capsule is in the form of granules or powders.

48. (Original) The formulation of claim 30 or 37, wherein each of said first and second components is provided as a separate dosage unit.

49. (Original) The formulation of claim 48, wherein each component is provided as at least one tablet.

50. (Original) A method for preparing a formulation which comprises (a) admixing nitrofurantoin monohydrate, hypromellose, alginic acid sodium alginate and at least one pharmaceutically acceptable carrier and forming said admixture into a controlled release first component; and (b) admixing macrocrystalline nitrofurantoin and at least one pharmaceutically acceptable carrier and forming said admixture to form an immediate release second component.

51. (Original) The method of claim 50, further comprising encapsulating said first and second components.

52. (Original) The method of claim 50, wherein each of said first and second components independently is in the form selected from the group consisting of granules and powders and wherein said components are formed into a single dosage unit.

53. (Original) The method of claim 50, wherein said dosage unit is a tablet.

54. (Original) The method of claim 53, wherein said first and second components are present as separate layers.

55. (Original) The method of claim 52, wherein said dosage unit is a capsule.

56. (Original) The method of claim 50, wherein each of said components is in the form of one or more tablets and said tablets are encapsulated within a single capsule.

57. (Original) The method of claim 55, wherein each of said components in said capsule is in the form of granules or powders and said components are present as separate layers.

58. (Original) The method of claim 55, wherein one of said components in said capsule is in the form of at least one tablet and the other of said components in said capsule is in the form of granules or powders.

59. (Original) The method of claim 50, wherein each of said first and second components is formed into a separate dosage unit.

60. (Original) The method of claim 59, wherein each component is provided as at least one tablet.

61. (Withdrawn) A method for treating a bacterial infection in a host which comprises administering to said host said formulation of claim 1, 30 or 37.

62. (Withdrawn) The method of claim 61, wherein said first component and said second component of said formulation are present in a wt:wt ratio of about 2:1 to about 3:1.

63. (Withdrawn) The method of claim 62, wherein said first component and said second component are present in a wt:wt ratio of about 2:1.

64. (Withdrawn) The method of claim 61, wherein nitrofurantoin monohydrate and macrocryststalline nitrofurantoin are present in a combined weight of about 100 mg.

65. (Withdrawn) The method of claim 64, wherein said formulation is administered two times per day for a period of about 7 days.

66. (Original) The formulation of claim 37, wherein at least one of said first and second components is coated.